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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,593	09/19/2005	Himangshu S. Bose	USCF.009.01US	9271
22798 7590 10/17/2007 QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			EXAMINER LIU, SAMUEL W	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 10/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,593

Applicant(s)

BOSE ET AL.

Examiner

Samuel W. Liu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim 1, drawn to a method of identifying a cellular location corresponding to the site of action of a cellular process comprising expressing a key protein in a cell-free translation system which comprises as organelle that is the target of the said action.

Group 2, claims 2-3, drawn to a method of identifying a mitochondrial compartment which is a bioactive site of a mitochondrial protein comprising cotransfecting a host cell with a first polynucleotide encoding the mitochondrial protein and a second polynucleotide encoding a receptor for said protein, and expressing said two polynucleotides.

Group 3, claims 4-6, drawn to a method of obtaining a receptor-ligand complex comprising mitochondrial leader sequence of a steroidogenic acute regulatory protein (StAR) and a receptor binding to said sequence comprising combining the StAR protein having the leader sequence with a source of said receptor.

Group 4, claims 7-11, drawn to an isolated mitochondrial StAR receptor binding protein.

Group 5, claim 12, drawn to a recombinant non-steroidogenic host cell.

Group 6, claims 13-14, drawn to a method of enhanced steroid production comprising transfecting a steroidogenic host cell with a nucleic acid encoding a bioactive StAR protein and immobilizing said protein on the cytoplasmic side of outer mitochondrial membrane, and growing said cell.

Group 7, claims 15-17, drawn to a method of producing pregnenolone in a non-steroidogenic animal cell comprising co-transfecting said cell with (i) the bioactive StAR protein and (ii) a nucleic acid encoding a cholesterol side chain cleavage enzyme, and growing the co-transfected cells.

Group 8, claim 18, drawn to a method of screening a compound which alter steroidogenesis comprising contacting non-steroidogenic cells comprising the protein "MLN64" that synthesizes a steroid hormone with a test compound.

The method of claim 1 is obvious over Janiak et al. (*J. Biol. Chem.* (1994) 269, 9842-

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9849). Prior to the effective filing date of the instant application, on Figure 3, and pages 9843, "Materials and methods" section), Janiak et al. teach identifying outer mitochondrial membrane "a cellular location" which is considered to be a part of the site of action of Bcl-2 mediated apoptosis "a cellular process" (see page 9842, right column, 1st paragraph) by incubating organelle mitochondria with in vitro translation mix wherein Bcl-2 protein "a key protein for apoptosis" is produced. Thus, Janiak et al. teach the instant method of claim 1. Furthermore, the step of Group 2: cotransfection two polynucleotides, the step of Group 3: forming leader sequence of StAR with a receptor; step of Group 6: immobilizing the protein; the step of Group 7: cotransfecting the StAR protein and the nucleic acid; and the step of Group 8: using MLN64 protein that involves in synthesis of steroid hormone are unique/distinct from one another. The Product/composition of Group 4 (protein) and Group 6 (cell) are also distinct from each other. Therefore, the claimed composition does not constitute a special technical feature linking all claims, as defined by PCT Rule 13.2 and 37 CFR 1.475(a), as a single contribution over the art, and a holding of lack of unity is therefore proper.

Additional Election Under 35 USC 121

Applicants are further required under 35 US 121 (1) to elect a single disclosed peptide or a nucleotide sequence encoding the peptide to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

If Group 4 is elected, applicant is required to elect following one protein list in claim 9, because the proteins, which constitute the "subunit" of the claimed mitochondrial StAR receptor binding protein in claim 9, e.g., adenine nucleotide translocator, aldehyde dehydrogenase and ATP carrier protein are structurally and functionally distinct from one another, these proteins hey do not overlap in scope and are not obvious variant from each other.

The response should also identify the claims readable thereon as directed to the elected invention.

It should be noted that this additional election of the restriction requirement is not species election but rather the additional election under 35 USC 121 since the above-mentioned proteins are distinct/different from one another in amino acid sequence and biological function.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

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- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.


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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon, can be reached on (571) 272-0931. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.


Samuel W. Liu, Ph.D.
Patent Examiner, Art Unit 1656
October 4, 2007


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER